FEB 16 2005

K050118

510(k) Summary

This 510(k) Summary for the EBI® Trochanteric Nail System is provided as required per Section 513(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Frederic Testa
Phone: (973)299-9300, ext. 2208

Date prepared: January 17, 2005

2. **Proprietary Name:** EBI® Trochanteric Nail System

Common Name: Internal Fixation Device

Classification Names: Rod, Fixation, Intramedullary and Accessories, 21 CFR 888.3020.

3. **Predicate or legally marketed device that is substantially equivalent:**

Biomet Holland Femoral Nail System (K983641)

4. **Description of the device:** The EBI® Trochanteric Nail System is an interlocking intramedullary rod used in the fixation of fractures of the femur. The system consists of five basic components; trochanteric nails, lag screws, cortical screws, end caps, and set screws.

5. **Intended Use:** The EBI® Trochanteric Nail System is intended to be implanted into the long bones for alignment, stabilization, and fixation of fractures caused by trauma or disease, the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity, and for athrodesis.

6. **Non-Clinical Testing:** The results of the mechanical testing demonstrate that the EBI Trochanteric Nail System is mechanically as strong as the predicate device.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI® Trochanteric Nail System and other currently marketed internal fixation systems. It is substantially equivalent* to the predicate device in regards to indications for use, location, design characteristics, material, mechanical strength, and sterility.

8. **Conclusion:** Technological characteristics and mechanical testing have demonstrated that the EBI Trochanteric Nail System is as safe and effective and performs as well as the predicate device and is therefore substantially equivalent.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

Mr. Frederic Testa, RAC
Regulatory Affairs Project Manager
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K050118
Trade/Device Name: EBI® Trochanteric Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Codes: HSB
Dated: January 17, 2004
Received: January 18, 2004

Dear Mr. Testa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

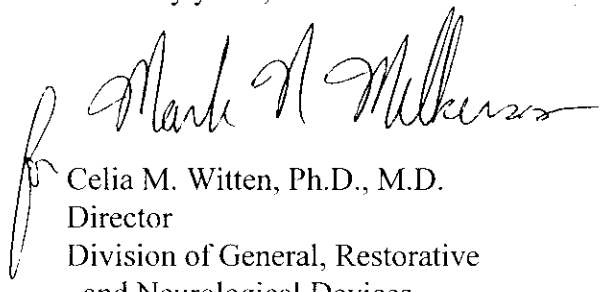
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: EBI® Trochanteric Nail System

Indications For Use:

The EBI® Trochanteric Nail is indicated for the treatment of fractures of the femur including: non-comminuted and comminuted midshaft fracture, subtrochanteric fracture, distal third fracture, combination fractures of the shaft and neck, intertrochanteric fracture, combination intertrochanteric and subtrochanteric fractures. The EBI Trochanteric Nail is also indicated for osteotomies, reconstructive procedures following tumor resection, revision procedures where other treatment or devices have failed, and arthrodesis.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K05 0118